IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
NO. 7:23-CV-00897

IN RE:

CAMP LEJEUNE WATER LITIGATION

This Document Relates To:
***McElhiney v. United States,* 7:23-cv-01368**
***Peterson v. United States,* 7:23-cv-01576**
***Rothchild v. United States,* 7:23-cv-00858**
***Sparks v. United States,* 7:23-cv-00682**
***Welch v. United States,* 7:23-cv-01503**

UNITED STATES' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF ITS MOTION TO EXCLUDE CERTAIN OPINIONS OF GARY MILLER, LUCIO COSTA, AND RICHARD BARBANO
(Fed. R. Evid. 702)

("Unreliable Exposure Opinions")

INTRODUCTION

Plaintiffs have failed to meet their burden to show, by a preponderance of the evidence, that the opinions of their experts, Drs. Gary Miller, Lucio Costa, and Richard Barbano, are reliable and admissible under *Daubert v. Merrell Dow Pharmaceuticals*, *Inc.*, 509 U.S. 579 (1993), and Federal Rule of Evidence 702. As detailed in the United States' opening brief,[1] Dr. Miller's and Dr. Costa's misstatement of the findings of Goldman, et al.'s *Risk of Parkinson Disease Among Service Members at Marine Corps Base Camp Lejeune* (hereinafter "Goldman 2023") undermines the foundations of their opinions on a specific threshold dose of Trichloroethylene ("TCE") that causes Parkinson's disease ("PD"), and renders the opinions unreliable and inadmissible under Rule 702. *See* U.S.' Mem. at 10–20, D.E. 548; Goldman 2023 (JA Ex. 253, D.E. 480-13). Similarly, Dr. Barbano's reliance on Dr. Miller's and Dr. Costa's unreliable opinions and his results-driven methodology make his own opinions unreliable and therefore inadmissible under Rule 702.[2]

Plaintiffs do not meaningfully respond to the arguments raised in the opening brief and instead attempt to use their opposition brief[3] to bolster their experts' opinions with a recitation of their credentials and allusions to other studies they reviewed in unrelated sections of their reports. Plaintiffs never directly address their experts' fundamental misinterpretation of Goldman 2023, or the ensuing analytical gap, *ipse*

[1] "Opening brief" refers to the United States' Memorandum in Support of its Motion to Exclude Certain Opinions of Gary Miller, Lucio Costa, and Richard Barbano, D.E. 548.

[2] Plaintiffs also admit in their response that Dr. Barbano offered untimely general causation opinions despite their insistence in other filings that Dr. Barbano is not offering general causation opinions. *Compare* Pls.' Opp'n. at 21, D.E. 682 ("Dr. Barbano also offers the *general causation* opinion that TCE and PCE are at least as likely as not to cause PD.") (emphasis added) *with* D.E. 688 at 7 ("Drs. Barbano, Schwarz, and Andruska are *not* independently opining on general causation, and Plaintiffs *are not* relying on their opinions for general causation."). The United States maintains that the Court's Jul. 22, 2025 Order clearly proscribed specific causation experts, such as Dr. Barbano, from offering general causation opinions disclosed at the deadline for specific causation reports when it stated that "permission [for specific causation experts to rely on general causation evidence] does not allow Plaintiffs to present new general causation theories, fresh literature reviews, or threshold calculations after the Phase II deadline." D.E. 444 at 4.

[3] "Opposition brief" refers to Plaintiffs' Leadership Group's Memorandum of Law in Opposition to Defendants' [sic] Motion to Exclude Certain Opinions of Gary Miller, Lucio Costa, and Richard Barbano, D.E. 682.

dixit, and results-driven methodologies, all of which make their opinions unreliable and inadmissible under Rule 702.

ARGUMENT

I. Bench Trials Do Not Strip Courts of Their Gatekeeping Function with Respect to Reliable Expert Testimony Under Rule 702.

Plaintiffs suggest that the Court should abdicate its gatekeeping role and provisionally admit unreliable expert testimony for later determination simply because these cases are bench trials, rather than jury trials. Pls.' Opp'n. at 7, D.E. 682 (quoting *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 833 (3d Cir. 2020)).[4] All case law that Plaintiffs cite for their proposition predate the December 2023 amendments to Rule 702. These amendments clarified that admissibility determinations are preliminary questions that the Court must decide under Rule 104(a), and that Rule 104(b), which allows the court to "admit the proposed evidence on the condition that the proof be introduced later," is inapplicable. Fed. R. Evid. 702 advisory committee's note to the 2023 amendments. The analytical gap in Plaintiffs' experts' reasoning leaves a gaping hole in their calculations of a specific threshold of TCE capable of causing PD for their determinations on specific causation. Therefore, it would be unreasonably prejudicial, confusing, and a waste of time to conditionally admit unreliable testimony on a precise causal TCE threshold for PD, even if it were to be subject to a later admissibility determination under Rule 702.

II. Dr. Miller's and Dr. Costa's Opinions on Causation Thresholds Are Unreliable Because They Rest on a Faulty Foundation that Overstates the Findings of Goldman 2023 and Are Methodologically Unsound.

Plaintiffs have failed to demonstrate that the exposure threshold opinions of Drs. Miller and Costa are based on sufficient facts and data and reliable methods. *See Daubert*, 509 U.S. at 597 (Rule 702 requires "that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"). Instead,

[4] Plaintiffs also filed a separate Motion to Reserve Admissibility Determinations and Expedite Track 1 Bellwether Trials. D.E. 721. For a full discussion of this issue, *see* United States' Response to Plaintiffs' Motion to Reserve Admissibility Determinations and Expedite Track 1 Bellwether Trials, D.E. 733.

Plaintiffs fall back on the empty *ipse dixit* of their experts.[5] While Drs. Miller and Costa may be qualified in their respective fields, their testimony with respect to a precise threshold dose of TCE that can cause PD fails to meet the reliability requirements of Rule 702.

A. Goldman 2023 Does Not Contain Sufficient Facts or Data to Support the Conclusions that Dr. Miller and Dr. Costa Claim to Draw from It.

Plaintiffs' desire for a study that links exposure thresholds to causation is understandable because "in order to carry the burden of proving a plaintiff's injury was caused by exposure to a specified substance, the plaintiff must demonstrate the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999) (internal quotations omitted). But Goldman 2023 is not such a study. As more fully explained in the opening brief, Goldman 2023 does not contain the necessary individual exposure information to draw conclusions regarding a causal threshold. *See* U.S.' Mem. at 10–14, D.E. 548.

Plaintiffs recharacterize the Fourth Circuit's requirement to demonstrate exposure thresholds as "flexible," s*ee* Pls.' Opp'n. at 6, D.E. 682, but flexibility does not grant experts permission to pull information from thin air while pointing to their "experience" as blanket justification. Indeed, "[t]rained experts commonly extrapolate *from existing data*." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (emphasis added). "But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert," *Id.*, thus "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered," *Id.*; *see also Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 851 (E.D.N.C. 2015)) (Flanagan, J.) ("[T]he general level of hazardous exposure need not be expressly established by a particular scientific

[5] Plaintiffs also raise arguments related to the reliability of the methodology and analysis of Dr. Miller's and Dr. Costa's opinions that TCE can cause PD. *See* Pls.' Opp'n. at 6–9, D.E. 682. While this Reply is limited to Plaintiffs' experts' analytical gap in their exposure threshold opinions, the United States does not concede that Drs. Miller's and Dr. Costa's methodology is reliable under Rule 702. Issues related to the reliability of the methodology and analysis of Dr. Miller's and Dr. Costa's opinions that TCE can cause PD were raised in the United States' Motion on Unreliable Literature Review. *See* U.S.' Mem. in Supp. of its Mot. to Exclude Plaintiffs' Parkinson's Disease Experts Drs. Steven Bird, Jason Cannon, Amelia Boehme, Gary Miller, Briana De Miranda, Lucio Costa, and Michael Freeman, D.E.542.

study, so long as the expert is able to establish that he uses a scientifically reliable method to *extrapolate the results from scientific literature*.") (emphasis added).

The analytical gap in Dr. Miller's and Dr. Costa's analysis stems from the fact that Goldman 2023 simply does not contain data to support the TCE threshold that Drs. Miller and Costa claim to draw from that study.[6] Plaintiffs' experts fail to explain how they can extrapolate an increased incidence of PD over a large cohort that averaged 25 months at Camp Lejeune and apply it, carte blanche, to all individuals at Camp Lejeune—including those that may have only been at Camp Lejeune for 90 days, which was the minimum amount time on base required for inclusion in the Goldman 2023 study population.

Indeed, Plaintiffs' experts ignore the realities of the study population. A minimum study criterion is a filter through which one gathers the relevant data; it is not a data point for interpreting the results of an analysis that includes individuals who were there for a much longer time period. In other words, a 70% higher *risk* of PD among individuals with *at least* 90 days of exposure is distinct from 90 days of exposure *causing* a 70% increase in PD. In the opposition brief, Plaintiffs concede that "'at least 3 months between 1975 and 1985' is a defining characteristic of the Goldman 2023 study design." Pls.' Opp'n. at 15, D.E. 682. Yet, Plaintiffs do not further explain the implications of this "defining characteristic" and simply reassert the conclusions of Dr. Miller and Dr. Costa. *Id*. at 13 ("'[T]he estimated dose required to increase the incidence of Parkinson's disease must be equivalent to the amount of exposure that would occur over 90 days' at Camp Lejeune between 1975 and 1985."). This does not constitute a reliable methodology.

Plaintiffs also claim that Goldman 2023's conclusions are "crystal clear." *Id*. at 14. The United States agrees that Goldman 2023 concludes that there was a 70% higher incidence of PD among a cohort of individuals who were at Camp Lejeune for an average of 25 months than a cohort of individuals who

[6] Tellingly, Plaintiffs' citations to Goldman 2023 in their opposition brief only point to the study's finding of a 70% higher risk of PD at Camp Lejeune compared to Camp Pendleton. Pls.' Opp'n. at 12, D.E. 682 (citing Goldman 2023 at 6784. The opposition brief does not contain a reference to Goldman 2023 that supports the experts' contention that 90 days of exposure as being sufficient for the increased incidence. *Id.* In reality, all references to Goldman 2023 claiming to find that 90 days of exposure causes the increased incidence in PD come from Dr. Miller's own testimony and report. *See, e.g.*, *id*. at 13 (citing Miller Rep. at 14 (JA Ex. 132, D.E. 467-15)).

were at Camp Pendleton for an average of 22.7 months.[7] Goldman 2023 at 676, Table 1 (JA Ex. 253, D.E. 625-17). But that is a far cry from concluding that 90 days at Camp Lejeune is sufficient to cause a 70% increase in PD for all individuals, including those with the minimum presence. Claiming that those statements are the same is indeed "nonsense" on Dr. Miller's and Dr. Costa's part. Pls.' Opp'n. at 14, D.E. 682.

Significantly, Goldman 2023 does not detail exposure data in any way that would allow Dr. Miller and Dr. Costa to extrapolate a causal threshold dose from it. Plaintiffs argue that the United States is demanding that Dr. Miller and Dr. Costa only rely on studies with individual exposure data for each veteran stationed at Camp Lejeune. This is a red herring. To the contrary, the United States is merely arguing that it is unreliable for Dr. Miller and Dr. Costa to claim that an increased risk of PD, calculated for a cohort with an average presence at Camp Lejeune of 25 months, applies to anyone who was there for three months or more. As explained in the opening brief, the fatal issue in purporting to determine a causal dose of TCE from Goldman 2023 is that Goldman 2023 only states an average time on base for the *entire* Camp Lejeune cohort and does not explain how individuals with PD compared to the cohort's average presence or any other known exposure duration. U.S.' Mem. at 11, D.E. 548. However, reaching the conclusions Dr. Miller and Dr. Costa desire would require the study include *some* analysis for exposure specific to the individuals who developed PD. Goldman 2023 contains no such analysis. Without this information, it is truly unknown whether the cohort individuals with PD were exposed to TCE or some other contaminant entirely. But Goldman 2023 merely uses presence on Camp Lejeune to assume that each individual experienced the same types and durations of exposures for the entirety of their time at the base. Goldman 2023 at 679 (JA Ex. 253, D.E. 480-13) ("we inferred exposure based on [presence at the] camp"). To reiterate, it is uncertain how long the Goldman 2023 cohort individuals that developed PD were exposed to contaminated water at

[7] The United States does not concede that Goldman 2023's conclusions are correct or valid or without limitations, it merely acknowledges that Goldman 2023's conclusion is clear and further acknowledges that issues of a study's correctness go to weight rather than admissibility. *See* Fed. R. Evid. 702 advisory committee notes to the 2000 amendments ("The evidentiary requirement of reliability is lower than the merits standard of correctness.").

Camp Lejeune (or even whether they were exposed at all) and, "[t]herefore, it is possible that the majority of individuals within the cohort who developed PD had more than 25 months of exposure, but Goldman 2023 did not provide that data." U.S.' Mem. at 11, D.E. 548. Yet, Dr. Miller's and Dr. Costa's interpretation of Goldman 2023 ignores this missing data and essentially presumes that each cohort individual with PD was on base for 90 days and experienced exposure of 366 micrograms per liter of TCE from every source of water during each of those days, making that a sufficient threshold dose level for a 70% increase in PD.

Accordingly, an expert claiming that Goldman 2023 proves "the estimated dose required to increase the incidence of Parkinson's disease must be equivalent to the amount of exposure that would occur over 90 days" at Camp Lejeune is an honest misinterpretation at best, or an intentionally misleading statement at worst. Miller Rep. at 14 (JA Ex. 132, D.E. 467-15). Whether intentional or not, "given the potential persuasiveness of expert testimony, proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *Westberry*, 178 F.3d at 261.

In addition, Plaintiffs' recounting of Goldman 2023's odds ratio, confidence interval, and other quantitative descriptors of significance and accuracy do nothing to resolve the fact that Goldman 2023 does not fit the purpose that Dr. Miller and Dr. Costa use it for, which is to establish a TCE exposure threshold that causes PD. Pls.' Opp'n. at 16, D.E. 682. Indeed, "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Daubert*, 509 U.S. at 591. As Plaintiffs admit, Goldman 2023, like all studies, has its own limitations, but no amount of "consider[ing] the limitations of Goldman 2023" can overcome the fact that it does not contain the type of data from which Dr. Costa and Dr. Miller claim to have extrapolated their conclusions. Pls.' Opp'n. at 19, D.E. 682. It remains Plaintiffs' burden to "demonstrate the levels of exposure that are hazardous to human beings generally as well as the plaintiffs actual level of exposure." *Westberry*, 178 F.3d at 263 (internal quotation omitted). Dr. Miller's and Dr. Costa's misinterpretation of Goldman 2023 falls woefully short of meeting that burden because they provide no evidence that is reliable for those who land on the lower end of the exposure spectrum, even assuming that Goldman 2023 is otherwise valid.

B. Dr. Miller's and Dr. Costa's Calculations Are Not Based on Reliable Methodologies.

Even if Goldman 2023 did offer the conclusion that Dr. Miller and Dr. Costa ascribe to it, their methodologies fail to stay within the bounds of what can be concluded from a reliable application of their methodologies. *See* Fed. R. Evid. 702 advisory committee note to 2023 amendment (stating that the 2023 amendment is intended "to emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology"); *see Nix v. Chemours Co. FC, LLC*, No. 7:17-CV-189-D, __ F. Supp. 3d __, 2025 WL 2924613, at *5 (E.D.N.C. Sep. 30, 2025) [hereinafter "*Nix II*"] (same).

1. Dr. Miller's Calculations Are Riddled with Unexplained Assumptions.

Dr. Miller's calculations are largely supported by *ipse dixit*. Dr. Miller's exposure calculations feature doubling, and then reducing, water consumption to account for dermal and vapor exposure without any discernable source to support the calculations. After purporting to calculate a precise dosage of TCE that can cause PD, Dr. Miller then arbitrarily reduced that dosage from 164.7 mg to 150 mg without any explanation. Plaintiffs allege that Dr. Miller's assumptions were based on the Agency for Toxic Substances and Disease Registry's ("ATSDR") reports, yet nowhere in his report does Dr. Miller indicate that his actual figures were from the ATSDR.[8] *Compare* Pls'. Opp'n. at 11, D.E. 682 *with* Miller GC Rep. at 14 (JA Ex. 132, D.E. 467-15) (referencing non-ATSDR studies). Nor did Dr. Miller identify the figures' sources when questioned at deposition, instead indicating that he would identify them later (though he never did). Miller GC Dep. Tr. at 156:10–157:8 (JA Ex. 171, D.E. 470-10).

[8] It bears noting that throughout their opposition brief, Plaintiffs routinely use vague descriptions in place of proper citations, leaving the United States and the Court to search and guess for the intended source. For example, Plaintiffs simply provide short cites to "ATSDR 2016" and "ATSDR 2017" without full citations. *See* Pls'. Opp'n. at 1, D.E. 682. Furthermore, there is no "ATSDR 2016" study related to Camp Lejeune. Based on the United States' searches and a review of Plaintiffs' experts' materials considered lists, it seems most likely that this is a reference to Maslia, M.L., Aral, M.M., Ruckart, P.Z., and Bove, F.J., *Reconstructing Historical VOC Concentrations in Drinking Water for Epidemiological Studies at a U.S. Military Base: Summary of Results*. Water 2016, 8, 449.

Dr. Miller also claimed that his figures were estimations "based on [his] knowledge of the volatility of these sorts of compounds and [his] general knowledge in toxicology." *Id*. at 160:14–19. Yet, he did not provide any support beyond this vague hand-waving to his experience. Finally, Dr. Miller admitted that, while he was aware that more sophisticated exposure models existed, he did not research them to use in his report. *Id*. at 162:3–25. "The Federal Rules of Evidence do not require a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Nix II*, 2025 WL 2924613 at *7 (citations and internal quotations omitted). Furthermore, "[w]ithout testing, *supporting literature* in the pertinent field, peer reviewed publications, *or some basis to assess the level of reliability*, expert opinion testimony can easily, but improperly, devolve into nothing more than proclaiming an opinion is true 'because I say so.'" *Id*. (emphasis added, citations and internal quotations omitted). Thus, Dr. Miller's faulty premise, unsupported inputs and assumptions, and decision to develop his own exposure model without considering other exposure models known to him render his methodology unreliable.

2. Dr. Costa's Methodology Skips Critical Steps.

Dr. Costa's methodology to determine a threshold concentration of TCE that causes PD suffers from two issues: a faulty foundation from his misinterpretation of Goldman 2023, and a failure to account for duration. While Dr. Miller at least attempted to account for dose, though he did so unreliably, Dr. Costa fails to account for dose at all and merely identifies a concentration level. The distinction is relevant because "the dose makes the poison" and concentration is only one element of a dose, which also must consider quantity and duration. *See Yates*, 113 F. Supp. 3d at 851 (citing Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 636 (3d ed. 2011)).

III. Dr. Barbano's Methodology to Support His Conclusions That PD Is Causally Tied to Alleged TCE Exposures at Camp Lejeune Is Unreliable and Outcome-Driven.

Plaintiffs' specific causation expert, Dr. Barbano,[9] improperly developed his opinions based on unreliable assumptions and with an outcome in mind. The issue is not, as Plaintiffs assert, that Dr. Barbano

[9] Dr. Barbano offered specific causation opinions in *McElhiney v. United States* and *Peterson v. United States*. This motion is limited Dr. Barbano's exposure threshold opinions. The United States separately

merely previewed his conclusion before discussing his methodology, but rather that his conclusion drove his methodology. "Result-driven analysis, or cherry-picking, undermines principles of the scientific method and is a quintessential example of applying methodologies (valid or otherwise) in an unreliable fashion." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 634 (4th Cir. 2018). Dr. Barbano's reports and deposition testimony reveal that he concluded that Mr. McElhiney and Mr. Peterson had "substantial exposure" without defining what constituted a substantial exposure. Moreover, Dr. Barbano conceded that he would have reached this conclusion regardless of the individual exposure circumstances. He testified, "[t]here really, in essence, is no safe level [of TCE], so the question [of PD causation] comes down to individual variability." Barbano Dep. Tr. at 195:12–14 (JA Ex. 610, D.E. 509-8). In other words, Dr. Barbano would still have found Mr. McElhiney's and Mr. Peterson's exposure to be "substantial" enough to cause their PD, regardless of the level and duration of exposure. But "without reliable scientific knowledge of what level of exposure to [a chemical] is needed to produce Plaintiffs' injuries, the experts can only speculate whether the level of Plaintiffs' exposure [to the chemical] was high enough to cause their injuries." *Zellars v. NexTech Ne., LLC*, 895 F. Supp. 2d 734, 741 (E.D. Va. 2012).

Plaintiffs' reiteration of Dr. Barbano's specific causation analysis is meaningless in regard to his testimony that any exposure to TCE is substantial enough to cause PD. Rather than engage in the issue before the Court—whether assuming that any exposure to TCE is the sole cause of someone's PD is a reliable methodology—Plaintiffs merely reiterate Dr. Barbano's differential diagnosis methodology. Plaintiffs assert that Dr. Barbano compared Dr. Miller's and Dr. Costa's causal doses to Dr. Reynold's exposure analysis. Pls.' Opp'n. at 22, D.E. 682 ("Dr. Barbano . . . noted that Mr. Peterson's exposure far exceeded the minimum exposure level determined by Drs. Costa and Miller[.]"). But Dr. Barbano's testimony makes clear that he would have reached the same conclusion regardless of their individual

challenged Dr. Barbano's methodology as an unreliable differential diagnosis. *See* U. S.' Mem. in Supp. of iIts Mot. to Exclude the General and Specific Causation Opinions of Drs. Richard Barbano, Heidi Schwarz, and Kristin Andruska, D.E. 544.

exposure levels. *See* Barbano Dep. Tr. at 195:4–22 (JA Ex. 610, D.E. 509-8). Further, as discussed above, Dr. Miller's and Dr. Costa's analyses were each unreliable determinations of causal thresholds, and, therefore, cannot form the bases of Dr. Barbano's opinions, even if he considered them. A "proffered expert . . . should address the validity of the opinions of the experts he relied upon and not just show an unblinking reliance upon the opinions of other experts." *Funderburk v. S.C. Electric & Gas Co.*, 395 F. Supp. 3d 695, 717 (D.S.C. 2019) (internal citations omitted). Dr. Barbano's specific causation testimony fails to meet the reliability requirements of Rule 702 because it is riddled with the same issues that plague Dr. Miller's and Dr. Costa's analyses.

CONCLUSION

For the reasons articulated in this Memorandum and in the United States' opening brief, the United States respectfully requests that this Court exclude the general causation opinions of Dr. Gary Miller and Dr. Lucio Costa regarding a specific threshold dose of TCE that can cause PD, and the specific causation opinions of Dr. Richard Barbano to the extent that he relied on the threshold dose opinions of Dr. Miller and Dr. Costa.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 12, 2025, I electronically filed the foregoing using the Court's Electronic Case Filing system, which will send notice to all counsel of record.

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